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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,090	07/22/2003	George A. Scheele	JHU1710-4	8783

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,090	SCHEELE ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-69 are pending, and are subjected to an election/restriction requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group(s):

I Claims 1-18, drawn to a method of making a pharmaceutical composition, wherein the composition comprises a lysate of an envelope virus, classified in class 435, subclass 7.2.

II Claims 19-25, drawn to a composition comprising a lysate of an envelope virus and a cholesterol-sequestering agent, classified in class 536, subclass 46.

III Claims 26-27 drawn to a method of inducing an immune response by administering the composition is Group II to a mammal, classified in class 435, subclass 7.2.

IV Claims 28-63, drawn to a method of treating viral infection with the administration of a cholesterol sequestering agent to a mammal infected or suspected of being infected by an envelope virus, classified in class 514, subclass 58.

V Claims 64-66, drawn to a method of generating an immune response in a mammal by contacting a population of lymphocytes in vitro with the composition of Group II to activate the lymphocytes, and administering the activated lymphocytes to the mammal, classified in class 435, subclass 7.2.

VI Claims 67-69, drawn to a method of treating viral infection in a mammal comprising the active method steps of removing blood from the mammal infected by an envelope virus; contacting the blood with an amount of cholesterol-sequestering agent to reduce viral load in the blood, and administering the reduced viral load blood to the mammal, classified in class 514, subclass 58.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions II-III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process for using that product, as evidenced by the invention of Group III and the invention of Group V. As set forth in the invention of Group III, the product administered to a mammal to induce an immune response; whereas, the invention of Group V sets forth a method of generating an immune response in a mammal by contacting a population of lymphocytes in vitro with product to activate the lymphocytes, and administering the activated lymphocytes to the mammal. The invention of Group III and the invention of Group V clearly set forth that the product as claimed can be used in a materially different process for using that product.

5. Inventions IV and VI are distinct from one another because: the inventions as claimed have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant, the invention of Group IV is directed at a method of treating viral infection with the administration of a cholesterol sequestering agent to a mammal infected or suspected of being infected by an envelope virus; whereas the invention of Group VI is directed at a method of treating viral infection in a mammal comprising the active method steps of removing blood from the mammal infected by an

envelope virus; contacting the blood with an amount of cholesterol-sequestering agent to reduce viral load in the blood, and administering the reduced viral load blood to the mammal. The inventions of Group IV and VI have materially different design and mode of operations, as evidenced by the different materials and active method steps required for each of the listed inventions.

6. Inventions of Group I, inventions of Groups III and V and the inventions of Groups IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). The invention of Group I is directed to a method of making a pharmaceutical composition, wherein the composition comprises a lysate of an envelope virus. The invention of Group I is not disclosed as capable of use together with the inventions of groups III and V. Nor is the Group I is disclosed as capable of use together with the inventions of groups IV and VI. Furthermore, the invention of Group I does have different designs and modes of operations than the inventions of groups III-VI. The invention of group I is directed to a method of making a product; whereas the invention of groups III-VI is directed at distinct methods of use for distinct products.

7. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. Furthermore,

it is noted that a different field of search would be necessary for each of the listed invention. For example, the field of search for the invention of Group I would be: method, make, lysate, envelope virus, and cholesterol-sequestering agent; whereas, the field of search for the invention of Group IV would be: treat, viral infection, cholesterol sequestering agent, and virus. Thus, because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

8. Additionally, if Applicant elects the invention of Group I and IV, the following election of species is also application:

For Group I: claim 1 is generic to the following disclosed patentably distinct species: Human immunodeficiency virus (HIV), Human herpes virus, Hepatitis virus, Pox virus, Influenza virus, Parainfluenza virus and Human T-cell lymphotropic virus (HTLV).

For Group IV, claim 28 is generic to the following disclosed patentably distinct species: Virus: Herpes virus 1, Herpes virus 2 and Poxvirus; Bacterium, Mycobacterium, Fungus and Protozoan.

9. The species are independent or distinct because the

The species are independent or distinct for the following reason(s):

Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

In the instant, each of the listed species is structurally very diverse from one another. The structural diversity noted also contributes to the diverse utilities that are noted for each of the listed species. Thus, the claims fail to comply with the Harnisch test for unity of invention.

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily Le
Patent Examiner
Art Unit 1648